REMARKS

Applicants wish to thank the examiner and her supervisor for their time spent preparing for and conducting the interview. During the interview, the parties discussed the written description rejections, as well as potential claim amendments that might overcome these rejections. Applicants thank the examiner for the courtesies extended during the telephonic interview. The contents of the interview are substantially incorporated herein.

Applicants cancelled claims 2, 3, and 24 without prejudice and reserve the right to pursue the subject matter therein in one or more divisional applications. Claims 1, 4-17, and 19 of the application have been amended. Claim 26 has been added. Claims 20-23 and 25 have been withdrawn by the examiner. With entry of this amendment, claims 1, 4-19, and 26 will be pending.

Claims 1, 4-17, and 19 of the application have been amended. The amendment to claim 1 finds support at least at paragraphs [0030], [0031], [0033], [0036], and [0037] of the published application, as well as original claims 2 and 3. Claims 4, 5, 12, 14, 17, and 19 are amended to remove multiple dependencies. Claims 6-11, 15, and 16 are amended to clarify that the recited % compositions are with respect to the total weight of the carrier, support for which may found at paragraphs [0029] and [0030] of the published application. Claims 5, 12, and 13 are additionally amended to replace "a" with "the" where appropriate. New claim 26 finds support at least at paragraph [0040] of the published application. No new matter has been introduced by way of these amendments.

Applicants additionally request entry of the amended paragraphs of the specification, which correct several errors in the molecular formulae given in paragraphs [0036] – [0038] of the published application. Applicants submit that the errors in the formulae would be self-evident to one of ordinary skill in the art, and that the amendments do not introduce any new matter.

Claim Objections

Claims 3-17 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because claim 3 is not in appropriate alternative form. Applicants respectfully submit that they have rendered this objection moot by canceling claim 3 and amending claims 4, 5, 12, 14, 17, and 19. Applicants respectfully request that the examiner withdraw these objections.

Rejections Under 35 U.S.C. § 112

Claims 1, 2, 18, and 24 are rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The examiner contends that the claimed subject matter is not sufficiently described in the specification to convey possession of the claimed subject matter, at the time the application was filed, to one of skill in the art. In particular, the examiner takes issue with the terms "derivative" and "complex" as used in the claims.

During the interview, the interview participants discussed adding the elements of claims 2 and 3 into independent claim 1 to overcome the written description rejections. The examiner and supervisor expressed an inclination to withdraw the written description rejection if such amendments were made.

The term "derivative" has been deleted from amended claim 1, and the lipophilic pharmaceutically acceptable compounds have been defined as being selected from the group consisting of tocopherol, vitamin A (retinol), vitamin K (menadione), tocotrienols, vitamin D (calciferol) and mixtures thereof. In other words, the elements of claim 2 have been added to claim 1. Additionally the "complexes" of the phosphorylated lipophilic pharmaceutically acceptable compounds have been further defined by incorporating some of the elements from claim 3 (namely arginine) and further defining the complexes with concise structural features. In view of the amendments, and the examiner and supervisor's previous willingness to withdraw the written description rejections if similar amendments were made, withdrawal of the 35 U.S.C. § 112, ¶ 1 rejection is respectfully requested.

Because claims 2 and 24 are cancelled, the rejection of claims 2 and 24 under 35 U.S.C. § 112, ¶ 1 is rendered moot. Claim 18 depends from independent claim 1 and recites additional features with respect to the carrier. For the same and similar reasons set forth above, withdrawal of the 35 U.S.C. § 112, ¶ 1 rejections is respectfully requested. Applicants respectfully request that the examiner withdraw all of the written description rejections.

Claims 1, 2, 18, and 24 are additionally rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the examiner takes issue with the use of the term "derivative." As set forth above, applicants have deleted the term "derivative." Because claims 2 and 24 are cancelled, the rejections of claims 2 and 24 under 35 U.S.C. § 112, ¶ 2 are rendered moot. Applicants respectfully request that the examiner withdraw all of the indefiniteness rejections.

Rejections Under 35 U.S.C. § 102

Claims 1, 2, and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,965,750 to Oonishi et al. ("Oonishi"). Oonishi describes a highly purified tocopheryl phosphate and/or a salt thereof ('the highly purified composition') which is soluble in water and highly stable, and a process for producing the same. Oonishi also discloses cosmetic preparations containing the highly purified composition which are free from precipitation of solid matter such as impurities and ensure high solubility in water and high preparation stability.

The cosmetic preparations may further comprise additional ingredients such as 'conventional emulsifiers' (see col. 15, line 66 to col. 16, line 5), which may encompass surfactants and anti-inflammatory ingredients (see col. 16, lines 38-57). Oonishi discloses that the conventional emulsifiers can be added in common considerations to the cosmetic preparation for the purpose of dissolving ingredients other than the tocopheryl phosphates and for the purpose of adding moisture retaining and cleaning capabilities which are fundamental to cosmetics. There is no teaching or suggestion that the emulsifiers can be used in a method for improving the efficacy and/or transdermal transport of topically administered pharmaceuticals and pharmacologically active compounds.

Furthermore, Oonishi does not teach or suggest claim 1's complexes. Specifically, Oonishi's emulsifiers do not fall within the scope of the complexes of claim 1. That is, they are neither arginine nor a substituted amine surfactant of the formula $NR^1R^2R^3$ wherein R^1 is chosen from the group consisting of straight or branched chain mixed alkyl radicals from C6 to C22 and carbonyl derivatives thereof, and R^2 and R^3 are chosen independently from the group consisting of –H, $-CH_2(CO)OX$, $-CH_2CH(OH)CH_2SO_3X$, $-CH_2CH(OH)CH_2OPO_3X_2$, $-CH_2CH_2(CO)OX$, $-CH_2CH_2CH(OH)CH_2SO_3X$, and $-CH_2CH_2CH(OH)CH_2OPO_3X_2$, wherein X is H, Na, K or alkanolamine provided R^2 and R^3 are not both H.

Because Oonishi does not teach all of the elements of claim 1, Applicants respectfully request that the examiner withdraw the rejection of claim 1 under 35 U.S.C. § 102(b). Because claims 2 and 24 have been cancelled, the rejection of claims 2 and 24 under 35 U.S.C. § 102(b) are rendered moot.

Claims 1, 2, and 24 are rejected under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(e), as being anticipated by WO 02/40033 to West ("the '033 application"). The '033 application discloses an emulsion composition comprising at least one mono-electron transfer agent phosphate derivative, at least one di-electron transfer agent phosphate derivative and a suitable carrier. The '033 application does not, however, teach or suggest incorporating a pharmaceutical or pharmacologically active compound in a carrier comprising an effective

amount of one or more complexes of a phosphorylated lipophilic pharmaceutically acceptable compound, as is recited in amended claim 1. In particular, the '033 application does not teach or suggest the complexing agents, as amended, or the use of the composition as a carrier for pharmaceuticals or pharmacologically active compounds. Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(e), is respectfully requested. Because claims 2 and 24 have been cancelled, the rejections of claim 2 and 24 in view of the '033 application are rendered moot.

Claims 1, 2, and 24 are also rejected under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(e), as being anticipated by WO 02/40034 to West ("the '034 application"). The '034 application discloses a composition comprising the reaction product of phosphorylated hydroxylated actives and complexing agents. The phosphorylated hydroxylated actives may be phosphorylated tocopherols. The '034 application does not, however, teach or suggest incorporating a pharmaceutical or pharmacologically active compound in a carrier comprising an effective amount of one or more complexes of a phosphorylated lipophilic pharmaceutically acceptable compound, as is recited in amended claim 1. In particular, the '034 application does not disclose the use of the compositions of the '034 application as carriers for the administration of pharmaceuticals and pharmacologically active compounds. Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(a), or alternatively under 35 U.S.C. § 102(e), is respectfully requested. Because claims 2 and 24 have been cancelled, the rejections of claim 2 and 24 in view of the '034 application are rendered moot.

Claims 1, 2, 18, and 24 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2004/0253318 to West ("the '318 publication"). The '318 publication discloses a method of treating a skin condition by topically administering a cosmetic or pharmaceutical topical formulation comprising phosphate derivatives of electron transfer agents. The phosphate derivatives of electron transfer agents, which may be tocopheryl phosphates, are the active component of the cosmetic or pharmaceutical topical formulation. The phosphate derivatives may be optionally reacted with a complexing agent that may be an amine surfactant. The '318 publication teaches that the cosmetic or pharmaceutical topical formulation may be applied either simultaneously, or shortly prior to, or after the application of, another active ingredient (see paragraph [0103] of the '318 publication).

The '318 publication also teaches that one type of preparation may comprise a two-component system wherein one component is an antibiotic in stable form and the other component comprises the phosphate derivatives of electron transfer agents (see paragraph [0107]). The '318 publication further teaches that another type of preparation comprises the two

active ingredients, stabilized to co-exist relatively unchanged at storage temperatures. These teachings teach away from the claimed invention which requires the step of incorporating the pharmaceutical or pharmacologically active compound in a carrier comprising an effective amount of one or more complexes of a phosphate derivative of a lipophilic pharmaceutically acceptable compound. Accordingly, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(e) is respectfully requested. Claim 18 depends from allowable claim 1, and is therefore allowable. Claim 18 may contain additional patentable subject matter for reasons not described herein. Because claims 2 and 24 have been cancelled, the rejection of claims 2 and 24 under 35 U.S.C. § 102(e) are rendered moot.

Applicants respectfully submit that the claims are allowable over the cited references. Applicants, therefore, respectfully request that the examiner withdraw all of the 35 U.S.C. § 102 rejections.

Claim 26 is newly added. Applicants respectfully point out that none of the cited prior art teaches a method for improving the efficacy and/or transdermal transport of topically administered pharmaceuticals and pharmacologically active compounds comprising incorporating the pharmaceutical or pharmacologically active compound in a carrier comprising an effective amount of one or more complexes of a phosphorylated lipophilic pharmaceutically acceptable compound, wherein the pharmacologically active compound is selected from the group consisting of narcotic analgesics including morphine and levorphanol, non narcotic analgesics including codeine and acetominophen, corticosteroids such as cortisone, anesthetics including propofol, antiemetics including scopolamine, sympathomimetic drugs including adrenaline and dopamine, antiepileptic drugs including fosphenytoin, anti-inflammatory drugs including ibuprofen, thyroid hormones and antithyroid drugs including thyroxine, phytochemicals including α-bisabolol, eugenol, silybin, soy isoflavones, iridoid glycosides including aucubin and catapol, sesquiterpene lactones including pseudoguaianolide from *Arnica chamissonis*, terpenes including rosmarinic acid and rosmanol, phenolic glycosides including the salicylates salicin, saligenin and salicylic acid, triterpenes taxasterol or α-lactucerol, and isolactucerol, p-hydroxyphenylacetic acid derivative taraxacoside, hydroquinone derivatives including arbutin, phenylalkanones including gingerols and shagaols, hypercin, and acylphloroglucides including xanthohumol, lupulone, humulone and 2-methylbut-3-en-2-ol, or a derivative thereof. Accordingly, applicants respectfully request the allowance of claim 26.

Double Patenting Rejections

Claims 1, 2, and 24 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of co-pending U.S. Patent Application Serial No. 10/498,684. Applicants acknowledge this rejection, but choose to defer a response until the claims of this application, or the 10/498,684 application, are otherwise in an allowable form.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Favorable consideration of the present application as amended is therefore respectfully requested. If a conference call would be useful in resolving issues arising from the filing of this communication, please contact the undersigned at the below-noted number.

Respectfully submitted,

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